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VIA ECF

The Honorable Joan N. Ericksen
District Judge, District of Minnesota
United States District Court
12W U.S. Courthouse
300 South Fourth Street
Minneapolis, MN 55415

RE: *In re Bair Hugger Forced Air Warming Devices Products Liability Litigation*
MDL No. 15-2666-JNE-DTS

Dear Judge Ericksen:

Defendants request permission to file a motion for reconsideration of the Court's denial of Defendants' general causation *Daubert* and summary judgment motions. ECF No. 1024. Should the Court deny reconsideration, Defendants request that the Court certify the following question to the Eighth Circuit under 28 U.S.C. § 1292(b): Did Plaintiffs carry their burden to demonstrate the admissibility of their experts' general causation opinions under *Daubert*? Now is an opportune time for appellate review of this central issue, given Plaintiffs' anticipated appeal in *Gareis*.

Reconsideration

Plaintiffs' medical experts' opinions rest on a three-legged stool, supported by: (1) Dr. Elghobashi's CFD, which purportedly shows that the Bair Hugger system disrupts "unidirectional" air flow; (2) Augustine-sponsored studies concluding that the Bair Hugger system harbors bacteria (the "dirty machines" theory); and (3) the McGovern study, the sole epidemiological study purporting to show an increased risk of PJIs with use of the Bair Hugger system. New evidence and the Court's ruling on Plaintiffs' "dirty machines" theory have now knocked out every leg of that stool.

(1) Elghobashi Confirmed that His CFD Does Not Establish General Causation. Drs. Samet, Jarvis, and Stonnington relied on Elghobashi's CFD for their conclusion that the Bair Hugger system disrupts the "forcefield" of laminar airflow that protects patients on the operating table. But at trial, Elghobashi dismissed the idea of a protective forcefield as "absolute rubbish" and "silly," and said those who advance the idea "don't know turbulence." Trial Tr. at 974:4-15. Elghobashi's trial testimony also confirmed that his CFD cannot establish causation in any case, because the boundary conditions do not reflect any real operating room. Elghobashi admitted that no CFD is reliable unless based on accurate boundary conditions. Trial Tr. at 910:22-911:13. Yet he did not set his boundary conditions based on an actual OR in any of the cases in the MDL. *Id.* at 947:18-952:17. The CFD therefore cannot be relied upon by Plaintiffs' medical experts to support their opinions that the Bair Hugger system causes deep joint infections in actual surgeries. General causation requires more than just demonstrating a theoretical possibility of causation. It means demonstrating that the Bair Hugger system causes PJIs in real surgeries. *See, e.g., In re Gen. Mots. LLC Ignition Switch Litig.*, 2017 WL 6729295, at *7-8 (S.D.N.Y. Dec. 28, 2017) (proof of general causation requires proof of real world occurrence).

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(2) The Court Has Now Ruled That the “Dirty Machines” Theory Is Inadmissible. In *Gareis*, the Court excluded Plaintiffs’ alternative “dirty machines” theory, finding that Plaintiffs lacked any scientific evidence to support it. ECF No. 306 at 3 (“[Plaintiffs’] have not, however, shown any pathogen coming out of the ‘business end’ of the Bair Hugger—the perforated blanket.”). The Court’s ruling, by implication, extends to every case in the MDL.

(3) Dr. Reed’s New Study Demonstrates that the McGovern Study Is Unreliable. Last month, Dr. Mike Reed (senior author of the McGovern study) and his colleagues published a follow-up to the McGovern study addressing the impact of MSSA screening. Jeans, et al. “MSSA screening and decolonisation in elective hip and knee arthroplasty.” *J. Infection* (2018). The study encompassed the same time period and same patients as the McGovern study. As the Court may recall, Defendants argued that introduction of MSSA screening near the end of the Bair Hugger-only period, and its use throughout the HotDog period, had a significant impact on infection rates in favor of the HotDog cohort. Plaintiffs’ experts responded that no study had shown that MSSA screening had a significant impact. That study now exists, and proves Defendants were correct. Using a multivariate analysis, the study demonstrates that the MSSA screening and decolonization reduced *staph aureus* infections by two-thirds, and the overall infection rate also went down by a statistically significant amount. While noting that “improvement in infection rates could have been down [sic] to other factors . . .,” the authors conclude that the “dramatic reduction in MSSA SSI [surgical site infections] . . . suggest that screening and decolonization was responsible.”

Without the CFD, the “dirty machines” theory, and the McGovern study, Plaintiffs’ medical experts lack scientific support for their general causation opinions. Their opinions should be excluded.

Certification under 28 U.S.C. § 1292(b)

Even if the Court concludes that reconsideration is not warranted, Defendants request the Court still grant Defendants permission to file their motion. Entry of an order denying the motion will allow Defendants to request certification under 28 U.S.C. § 1292(b). The criteria for § 1292(b) certification are satisfied. First, admissibility of Plaintiffs’ medical causation experts turns on the controlling legal question of whether the standard is reliance on “scientifically valid evidence,” *Glastetter v. Novartis Pharms. Corp.*, 252 F.3d 986 (8th Cir. 2001), or the more permissive standard cited in the Court’s order. ECF No. 1024 at 3 (“Only if the expert’s opinion is so fundamentally unsupported that it can offer no assistance to the jury must such testimony be excluded.”¹ (quoting *Children’s Broad. Corp. v. Walt Disney Co.*, 357 F.3d 860, 864 (8th Cir. 2004))). Plaintiffs’ medical experts’ opinions are inadmissible under *Glastetter*. Second, there is substantial ground for difference of opinion, as the conflicting 8th Circuit standards show. Third, certification would materially advance the termination of the litigation. If the 8th Circuit agrees *Glastetter* controls, Plaintiffs’ experts’ opinions must be excluded and summary judgment granted.

Sincerely,

s/Benjamin W. Hulse

Benjamin W. Hulse

¹ This permissive language traces its origins to pre-*Daubert* 8th Circuit decisions.